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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,786	10/17/2003	Puranam Usha Sarma	41144F0071	1769
441	7590 11/08/2006		EXAMINER	
SMITH, GAMBRELL & RUSSELL 1850 M STREET, N.W., SUITE 800			BERTAGNA, ANGELA MARIE	
	ON, DC 20036	ART UNIT	PAPER NUMBER	
			1637	

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
`		10/686,786	SARMA ET AL.				
	Office Action Summary	Examiner	Art Unit				
	•	Angela Bertagna	1637				
	The MAILING DATE of this communication app	ears on the cover sheet with	the correspondence address				
Period fo	• •						
WHIC - External after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNIC, 36(a). In no event, however, may a reput apply and will expire SIX (6) MONTI, cause the application to become ABA	ATION. By be timely filed S from the mailing date of this communication. NDONED (35 U.S.C. § 133).				
Status	<u>.</u>						
1)[Responsive to communication(s) filed on 10 O	<u>ctober 2006</u> .					
2a)⊠	This action is FINAL . 2b) This	action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D.	11, 453 O.G. 213.				
Disposit	on of Claims						
,	Claim(s) <u>1-6</u> is/are pending in the application. 4a) Of the above claim(s) <u>5 and 6</u> is/are withdra Claim(s) is/are allowed.	awn from consideration.					
	Claim(s) <u>1-4</u> is/are rejected.						
·	Claim(s) is/are objected to.		·				
8)□	Claim(s) are subject to restriction and/o	r election requirement.					
Applicat	ion Papers						
9)[]	The specification is objected to by the Examine	₽ Г .					
	The drawing(s) filed on is/are: a) acc		y the Examiner.				
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)	The oath or declaration is objected to by the Ex	caminer. Note the attached	Office Action or form PTO-152.				
Priority (under 35 U.S.C. § 119						
	Acknowledgment is made of a claim for foreign ☐ All b)☐ Some * c)☐ None of:	priority under 35 U.S.C. §	119(a)-(d) or (f).				
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
	3. Copies of the certified copies of the prio		eceived in this National Stage				
	application from the International Burea		nanivad				
* See the attached detailed Office action for a list of the certified copies not received.							
		•					
Attachmer		_	(979.465)				
	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)		mmary (PTO-413) /Mail Date				
3) 🔲 Info	mation Disclosure Statement(s) (PTO/SB/08)	5) Notice of In	ormal Patent Application				
Pap	er No(s)/Mail Date	6) Other:	_·				

FINAL REJECTION

Status of the Application

1. Applicant's response filed October 10, 2006 is acknowledged. Claims 1-6 are currently pending. Claims 5 and 6 are withdrawn.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/102,731, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant claims 1-4 are not adequately supported by the prior-filed application 10/102,731, because the instant claims are directed to a method comprising amplification of exon IV of the human SP-A2 gene and determining the frequency of SNPs at positions 1649 and 1660, whereas the '731 application is directed to a method of amplifying the exon II region of the human SP-A2 gene and determining the frequency of SNPs

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at positions 1629 and 1640. Accordingly, benefit of the prior-filed application has not been granted, and the instant application filing date of October 17, 2003 has been used for prior art purposes.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Saxena et al. (Journal of Allergy and Clinical Immunology, May 2003; cited in IDS).

The instant claims are drawn to a method of detecting a predisposition to allergic bronchopulmonary aspergillosis (ABPA) based on the frequency of SNPs at positions 1649 and 1660 in exon 4 of the human SP-A2 gene.

Regarding claim 1, Saxena teaches a method of detecting a predisposition to allergic bronchopulmonary aspergillosis, comprising:

- (a) designing primers capable of amplifying exon 4 of the human SP-A2 gene (Table 1 and page 1002, "polymerase chain reaction" section).
- (b) amplifying genomic DNA of allergic bronchopulmonary aspergillosis patients and normal control subjects using the primers of step (a) (page 1002, Methods section)

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- (c) sequencing the amplified genomic DNA and identifying sequence variations computationally by comparing with an existing sequence of human SP-A2 DNA (page 1002 "Purification of PCR products and sequencing" section)
- (d) screening normal control subjects and allergic bronchopulmonary aspergillosis patients for SNPs using the primers of step (a) (page 1002 "Purification of PCR products and sequencing" section)
- (e) computing the frequency of G/C haplotypes at position 1649 and A/G haplotypes at position 1660 of the allergic bronchopulmonary aspergillosis and normal control subjects (page 1002 "Statistical analysis" section; see also Figure 1)
- (f) establishing the association of G (at position 1649) and G (at position 1660) haplotypes with allergic bronchopulmonary aspergillosis disease based on their frequency distribution in the normal and afflicted patients (page 1003, column 2)
- (g) predicting the risk or susceptibility to allergic bronchopulmonary aspergillosis based on the haplotype present at the polymorphic sites in the test subjects, where C at position 1649 and A at position 1660 is low risk and G at both position 1649 and 1660 is high risk (page 1003, column 2).

Regarding claims 2 and 3, Saxena teaches primers that correspond exactly to the instantly claimed primers for amplification of exon 4 of the human SP-A2 gene (see Table 1, primers 5 and 8). These primers are 30 nucleotides in length.

Regarding claim 4, Saxena teaches that the SP-A2 gene has allele variants that have G/C and A/G haplotypes (see abstract).

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Response to Arguments

Objection to the Specification

Applicant's arguments, see page 8, filed October 10, 2006, with respect to the objections to the specification have been fully considered and are persuasive. The objections to the specification have been withdrawn.

Rejection under 35 U.S.C. 102(a)

Applicant's arguments filed October 10, 2006 have been fully considered but they are not persuasive. Claims 1-4 were rejected under 102(a) as anticipated by Saxena et al. (Journal of Allergy and Clinical Immunology (May 2003) 11(5): 1001-1007. Applicant argues that this publication is not prior art and relies on the Oath/Declaration submitted with the instant application papers on March 18, 2004 as evidence that the work presented in the above article is solely the work of the inventors of the instant application (see pages 8-9 of the response). This argument is not persuasive, because in order to demonstrate that the material in the Saxena article is only the work of the instant inventors (i.e. not by "others"), Applicant must file an affidavit under 37 CFR 1.132 (see MPEP 716.10). Reliance on the originally filed oath/declaration is not sufficient to demonstrate that a prior art reference is not by "others", and therefore, the rejection of claims 1-4 under 35 U.S.C 102(a) as anticipated by Saxena has been maintained.

Conclusion

No claims are currently allowable.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F. 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna Examiner, Art Unit 1637 November 1, 2006

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